REMARKS/ARGUMENTS

The April 8, 2004 Office Action has rejected all pending claims (17 – 33). The Office Action proffers double patenting rejections and rejects claims 26 – 32 under 35 U.S.C. § 112 and all claims under 35 U.S.C. § 103(a). In light of the amendments above and the arguments below, Applicants respectfully request reconsideration.

Double Patenting

On page 2 of the Office Action, the Examiner proffers double patenting rejections over "co-pending application Nos. 09/465,300; 09/466,582; 09/599,364; 09/281,209; and 09/948,807 . . . ." The Examiner notes that these rejections are maintained from a previous Office Action. Applicants believe that this rejection is in error. The cited applications seem to have nothing to do with Applicants' invention and are not co-owned by Applicant.

On page 3 of the Office Action, the Examiner rejects claims 17 – 25 as rejected under the judicially created doctrine of obviousness-type double patenting over claims 1 – 16 of co-pending application No. 09/878,797. Applicants have addressed this rejection in a previous Office Action response (dated June 20, 2003) and repeat that application No. 09/878,797 has been abandoned.

§ 112 Rejections

Claims 26 – 32 are rejected under 35 U.S.C. § 112 on the ground that the specification "while being enabling for cytokines, does not reasonably provide enablement for all immunomodulatory agents." Although Applicants neither agree nor acquiesce with the Examiner's characterization of the specification, in the interests of speedy prosecution

Applicants have amended independent claim 26 to "cytokines." Claim 33 has been cancelled as being duplicative.

On page 7 of the Office Action, claims 26 – 32 are rejected on the ground that "the claims as written read on a multitude of possible immunomodulatory agents." Applicants have now clarified that these claims are limited to "cytokines."

§ 103 Rejection

The Office Action has rejected claims 17 – 33 under 35 U.S.C. § 103(a) as being unpatentable over Myers, et al. (U.S. Pat. 5,602,184) in view of Gould, et al. (U.S. Pat. 5,587,402). The Examiner cites Myers, et al. as disclosing a method of sensitizing cancer to radiation by administering terpenes. Applicants agree with the Examiner that "the reference fails to disclose specific chemotherapeutic agents and cytokines useful with their invention."

Gould, et al. is cited as disclosing the regression of mammalian cell tumors with perillyl alcohol. The Examiner notes that Gould, et al. disclosed the use of cytokines in particular experiments.

Applicants do not agree with the Examiner that it would be obvious to one of skill in the art to modify the invention of Myers, et al. by using the teaching of Gould, et al. Myers teaches the effectiveness of combining a terpene with radiation. Gould teaches the effectiveness of the terpenes themselves. Neither references speaks to the combination of the terpene with chemotherapeutic methods. Applicants agree with the Examiner that "Gould, et al. disclose that the monoterpenes themselves are chemotherapeutic agent candidates and the use of cytokines" but Gould does not speak to the sensitization of tumor cells by combining the terpene and other chemotherapy agents.

Neither piece of cited art relates at all to the combination of terpenes such as perillyl alcohol with any therapeutic mode other than radiation therapy. Neither piece of cited art would make treatment with terpenes such as perillyl alcohol obvious to combine with chemotherapy because neither piece of prior art cites any particular advantage or usefulness of such a combination. The references are simply silent on this subject. The teaching that one may successfully sensitize cancer cells to chemotherapy treatment by administering monoterpenes or sesquiterpenes is found within the present invention.

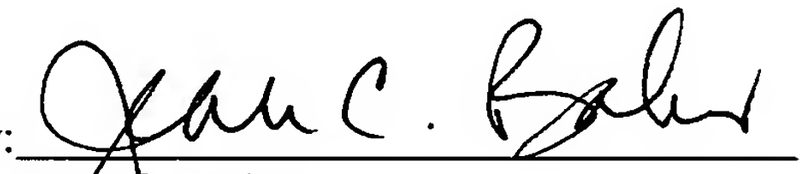
Although the cited Gould, et al. patent does disclose the use of cytokines, Applicants argue that the Gould, et al. patent disclosure teaches away from the present invention. Gould, et al. patent suggests an antagonistic effect of the terpene with the growth proliferating cytokine.

In their study, Gould, et al. demonstrate that addition of a growth promoting cytokine Interleukin 3 (IL3) to the leukemic cells under study along with perillyl alcohol (POH) neutralizes the growth inhibitory effects of POH. The observed growth inhibition is lost in the presence of the cytokine. This could mean that the growth inhibition seen by POH treatment is transient which could be overcome by the addition of a cytokine that allows cell proliferation. The conclusion from this work would be that POH is an effective chemotherapeutic agent and its growth inhibitory function may be reversed by cytokines. The reference does not teach the augmentation of cell death in the presence of cytokines. Thus, the use of terpenes with a chemotherapeutic agent or with a cytokine is not a logical interpretation of the studies conduced by Gould, et al. and Myers, et al.

Applicants believe that the currently amended claims are in condition for allowance and request speedy allowance. Applicants enclose a Petition and Fee for Three Months Extension of Time. If any other fees are necessary, please charge Deposit Account 17-0055.

Respectfully submitted,

Michael N. Gould, et al.

By: 

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